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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,424	04/13/2001	Stuart L. Schreiber	331D USD1	5917

24280 7590 01/14/2009
CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

EXAMINER	
VOGEL, NANCY TREPTOW	
ART UNIT	PAPER NUMBER
1636	

NOTIFICATION DATE	DELIVERY MODE
01/14/2009	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STUART L. SCHREIBER and GERALD R. CRABTREE

Appeal 2007-3483
Application 09/834,424
Technology Center 1600

Oral Hearing Held: September 9, 2008

Before TONI R. SCHEINER, DEMETRA J. MILLS,
and ERIC B. GRIMES, *Administrative Patent Judges.*

ON BEHALF OF THE APPELLANT:

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P R O C E E D I N G S

MS. BOBO-ALLEN: Good morning.

JUDGE SCHEINER: Good morning.

MS. BOBO-ALLEN: Calendar Number 1, Appeal Number 2007-3483. Mr. Berstein.

JUDGE SCHEINER: Thank you.

MS. BOBO-ALLEN: Um-hum.

JUDGE SCHEINER: Good morning.

MR. BERSTEIN: Good morning.

JUDGE SCHEINER: Would you like to introduce your colleague for the record?

UNIDENTIFIED: Your Honor, I'm not actually moving in.

JUDGE SCHEINER: That's okay.

MR. BERSTEIN: So I'm David Berstein and I'm Chief Patent Counsel at Ariad Pharmaceuticals. We're the exclusive licensee of this Patent Application. With me is Brenda Jarrell who worked closely with me on the prosecution. And I've never done this before, so I'm a little nervous --

JUDGE SCHEINER: Don't be.

MR. BERSTEIN: -- and I'm not sure what the formalities are. If I have any gaffs, it's unintentional. What I want to -- so there are two outstanding rejections. There's an art rejection and a written description of the invention rejection.

The art rejection is, to us -- we feel that we've traversed it pretty clearly in our papers, and my suggestion is that I would spend most of my time on the written description part of it, which I think raises much more interesting questions.

JUDGE SCHEINER: That's fine.

MR. BERSTEIN: Okay. So, the Examiner -- this is one of those cases where the Examiner felt that the invention wasn't disclosed in a way that conveyed possession of the invention by our inventors to the reader, the skilled artisan reading this document. And so we know from the case law, the evolution of the case law, the written description generally requires some level of detail in the description to convey that possession to the reader, and it's been explored in lots of different contexts. You know, the DNA famous cases and those different cases, those different inventions and circumstances have lead to a number of different formulations of the standard that -- or a test that is applied under those circumstances, depending on the kind of invention, and we see different kinds of issues or tests that are applied for different kinds of inventions, and that's -- because of that, because it's a written description of the invention, that's necessarily a fact- based, case-by-case analysis.

So in our case, our invention has to do with, with re-signaling in cells through receptors, and a lot of -- I think a lot of the early work on receptors had to do with understanding that protein growth hormones inside a kind bind to their receptors and signal. And there was basic research to understand how this works, to try to understand the mechanism, and a lot of work went on to find inhibitors of this kind of signaling, inhibitors for situations like cancer or inflammation. And in fact, my company was founded to do that. Many others were. Many pharmaceutical groups worked to come up with inhibitors of signal transduction to block signaling through these receptors.

This invention is different. This invention has to do with providing small molecule dimerizing agents that will activate signaling, and it's, it's very different. It takes advantage of one very cool distinction. When you're trying to make an inhibitor of a receptor, it's a -- clearly, it's a -- people use actually like crystal structures, computer modeling. It's a -- it is an intensive effort of design, to design something that has the exquisite binding characteristics that will inhibit the complex structure of a given protein.

Our situation is different. Our situation is based on the realization that -- in part, based on the realization that a simple binder could bind. It doesn't have to bind to a specific place on a protein, on a protein receptor. It doesn't have to bind in a particular manner. The cool part is that it just has to stick. And if you have -- take an antagonist or take any molecule that sticks relatively indiscriminately, has sufficient level of affinity, just a binder, stick them together covalently and there's your dimerizing agent for a receptor.

And so that's, that's our invention. You've -- I know you've seen from our specification, from the background of the invention, and from the prosecution, a lot has been written about dimerization and it's mechanistic role in signaling and how you can trigger it using our -- you know, how you can come up with triggers using our, our method.

So to apply the written description requirement to our invention, and you have to -- to me, looking -- I think having read the cases, thinking about their inventions, then looking at our invention, I think that to apply the test you want to get into the mind of the person of ordinary skill in the art reading the document and say can this person envisions this invention, examples of this invention.

To me, that means can this person see, envision using the different -- all the different binding technologies to font, pull out a binding agent, use the description of the different receptors and different types of receptors to take molecules off the shelf that you can link together. All the different variations of carrying out the steps of our method, that is what I think is important to think about when you put yourself in the mind of the practitioner. Is that person going to think of those, those aspects of, say, Claim 8? What binding techniques do I use in my lab and whatnot?

And I think a lot of the cases that we read there's a lot of conjecture about what the person of ordinary skill in the art can envision when reading a given document, whether it's a DNA invention or, you know, the Cox2 case. In our case we actually have, we have evidence of what the person of ordinary skill in this art does think, does imagine and does envision, and that came through in some of the papers that were cited in our prosecution. One of them is Austin, who actually says -- in talking about this dimerization approach, he actually says one can now imagine using binders to do this, and says that with the advent of modern screening technologies to find simple binders, this is now an open door, this is now something one can envision. And --

JUDGE MILLS: Weren't all the references that you cited in support of written description postfiling date references?

MR. BERSTEIN: That is Austin. I believe that's a postfiling date reference, yes.

MS. JARRELL: It's November '94. Austin, Qureshi, and I don't remember how to pronounce that.

MR. BERSTEIN: Tian. Right, Austin is November of '94. I think we have -- it's -- I think our filing date for --

MS. JARRELL: It's November 1st.

MR. BERSTEIN: We have a November 1 filing date, and Austin is a later November publication date. But the other two references are post, post that. One of them in particular is Qureshi, and in that document, that's the one where the researchers took the erythropoietin (Epo) receptor and they took one of their antagonists with competent binds to it, linked a number of those molecules together to make the dimerizing agent. It demonstrated the point of our invention with the epo receptor, and then they had a great conclusion where they actually expressed what their mental state was and what their expectations were, because they said that these data, they validate the concept both for their receptor and they also said by extension to most cited kind receptors and actually generalized it from their example.

And I think it's -- I think that's, that's telling because that's the actual words of somebody of skill in this art.

MS. JARRELL: Just to interrupt, if it's helpful, Austin was Exhibit D to the Brief.

JUDGE MILLS: Under what authority can we use the postfiling date references to show a written description at the time the invention was made? Didn't the Examiner discount all the exhibits that you provided because they were postfiling date references and they were not references available to one of ordinary skill in the art at the time the application was filed, so they'd be unable to support your written description argument?

MR. BERSTEIN: Right, but I think, I think one thing I could say about that is that the spec itself actually lays out the same point, that our spec says this. It makes the point that it's generalized, though it has the diagrams. It has diagrams that are preferably applicable to Qureshi. So these -- we have the words of our inventors who say this is the sort of structure function correlation that underlies this invention.

We have now a document, Austin, which is, you know, within weeks later saying much the same thing Qureshi a couple of years later -- I think Qureshi is of the late 90s. But they -- I think they're corroborating what the inventor said in their spec. It's -- it wasn't said for the first time by Qureshi and Austin and Tian. Our guys said it first. That was their -- that's their invention that they, they put this together.

JUDGE MILLS: Yes, you had argued in the Brief that you used competitive inhibition to link the binding domain to determine if the small dimerization molecule would competitively inhibit with ligand.

MR. BERSTEIN: Pardon me?

JUDGE MILLS: Your specification indicates that the method that you use to obtain the small dimerizing molecule is competitive inhibition with the ligand-binding domain for the receptor.

MR. BERSTEIN: That's one of them, yes. I mean, the specification does say you can take an antagonist and link them to -- and link two molecules together or multiple molecules together, which is what Qureshi did later. Did that answer your question?

JUDGE MILLS: I believe so. I was a little concerned that you had said before that your small dimerizing molecule was not really specific for

any location in the receptor, and then, then we have -- when you use your competitive inhibition you're actually looking for the ligand-binding domain.

MR. BERSTEIN: It doesn't have to. The molecule doesn't have to have the exquisite fit that an allosteric inhibitor has to have, or a ligand itself, a protein ligand. It doesn't require that, but they can be that. They can be -- you can take something that binds to any -- to many places on the protein. I think there are actually examples in some of the cited papers on using antibodies, I think with the EGFR receptor, demonstrating the point that you could have antibodies to different epitopes that caused dimerization of that receptor, and it wasn't a phenomena that required the specificity of -- that's the cool part of this, that it doesn't require that kind of specificity to get your impact.

JUDGE MILLS: Okay.

MR. BERSTEIN: There are many solutions to, to that question using this approach. So -- and in this sense, I think because our method is this way, because our -- what is required to carry out this method, finding simple binders, molecules that stick, because that's -- where was I going? -- that -- right. It's, it's, it's a different type of invention than a -- you know, you look at the -- I know they're not binding, but the, the training materials from the PTO have so many different examples that have been analyzed representing a lot of case law that represent a lot of different variations of different inventions that this requirement has been applied to. In our case, we're not those inventions. We're not, we're not claiming a class of compounds like Rochester. We're not claiming using a class of compounds like Rochester.

We're claiming a method of preparing things. And I was -- in reading Rochester, you know that the Court in Rochester said this specification, even though they didn't have one example of their selective inhibitor and they didn't show any -- they didn't try to show a structure-function relationship that the CFC said that what this specification does support are the screening methods.

That was clear, that screening method claims were okay, and Rochester does have their other patents. And the reason for that is the screening, that part of it was described, was adequately described that people could reading that envision ways of carrying out the screening. And I think what I'm submitting is that when the person of ordinary skill reads our document that person can envision ways of carrying out the method of preparing these, these dimerizing agents, and that should be the test. That should -- I think, that should be what we focus on: Can the person reading this actually envision ways of doing that rather than the Rochester situation? I think that's an important distinction. That's what makes it an interesting written description question, because I didn't see any other cases that were other than a substance or method of using the substance, and this is different. This is a method of preparing.

JUDGE GRIMES: You said that you didn't need any particular level of specificity for a site on your target proteins, but you do need to have some kind of specificity for the proteins that you're targeting, correct?

MR. BERSTEIN: Yeah, I think that's right. The molecule has to bind. It has to bind at some level, and the specification has some levels of affinity that --

JUDGE GRIMES: And, and it has to bind specifically to the two molecules that you're trying to bring together?

MR. BERSTEIN: Yes, it has to be able to bind to the two molecules.

JUDGE GRIMES: It can't be just a generic cross-linking agent because that would just cross into everything, correct?

MR. BERSTEIN: Right, that's right. This is not like glutaraldehyde or something, yes.

JUDGE MILLS: As to the binding issue that you just mentioned, I know that the record shows that there was some back and forth with the Examiner as to how the Examiner was reading the binding language and wasn't reading the binding language to encompass the affinity disclosed in the specification. Can you give us a reason why we should read the specification affinities into that binding language in the claim?

MR. BERSTEIN: You're referring to the art rejection?

JUDGE MILLS: Yes, also.

MS. JARRELL: It could be on versus --

MR. BERSTEIN: Right, I think that -- so, in reading our document, we're reading a document of cell biology, of ligands binding to receptors and molecules binding to receptors in a cell biology sense. And bind is the word that is -- is one of the words that's used in that field to describe the non-covalent bind to form a complex binding of GCSF with its receptor. I think it said GCSF binds with its receptor. Epo binds to its receptor. I think the word bind is used in this art in that sense.

I understand it's used -- in a bio-chemistry sense, it can be used to connote covalent detachment when that's appropriate for that context. In

our context, though, because we do talk about dissociation constants, because we're talking about receptor ligand interactions, I think it's very clear to the person in this art what we're talking about.

There, there -- certainly, there's language in the specification that we, that we would have -- we would have considered amending that language. We didn't really believe that that was necessary because of the context and the way we used the term. The specification does say "bind". You know, I think it certainly has dissociation constants which are inconsistent with covalent attachment, and it talks about binding to form complexes. And we could have amended to use other language to make that clearer if, if we thought that was important or necessary.

MS. JARRELL: Some of the claims actually also have the dissociation constant.

MR. BERSTEIN: That's right.

MS. JARRELL: You can't dissociate a covalent bond, so that's sort of a timative (phonetic sp.) dissonance. Not sure why the Examiner used it as a constant.

JUDGE MILLS: Were they -- did you argue those claims separately in the Brief?

MS. JARRELL: We did.

MR. BERSTEIN: Actually, I don't know if this qualifies for Claim differentiation, I don't know if that ever works out in a situation, but if you have a claim, a Dependent Claim that refers back to Claim 1 where in it it has a dissociation content of more than this or less than that, perhaps that does further that understanding or clarifies that that's what we're talking

about. We're talking about things that dissociate at some level and here in Dependent Claim whatever it's at this level.

I don't know if you find that satisfying an answer.

MS. JARRELL: It's Claim 15 that has the dissociation constant. And I'll just confirm that it is on Page -- yes, on Page 8 it indicates Claim 15 stands or falls upon. In fact, actually many of the claims -- I think part of -- since we are dealing with the written description and as we've said already fact-based inquiry based on what the invention is, we have many different inventions in the different claims. You have different, different scope, inventions of different scopes, so it's a different fact-based inquiry, right, some of the claims are to particular receptors, right. Claim 10, for example, calls our cited kind growth factor hormone receptors, particular sets of receptors about which there's an extensive literature binding agents that are known so on and so forth. Anyway, so, so for that reason, we had most of the claims stand and fall alone.

JUDGE MILLS: Okay, I believe I understand --

MR. BERSTEIN: Okay.

JUDGE MILLS: -- your position.

MR. BERSTEIN: Any other questions, or?

JUDGE MILLS: I don't think so.

JUDGE SCHEINER: I don't have any.

JUDGE MILLS: No, thank you.

MR. BERSTEIN: Thank you, very much.

JUDGE MILLS: It was very helpful.

MS. JARRELL: Thank you for your time.

(Whereupon, the hearing concluded at 9:20 a.m. on September 9, 2008.)